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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/057,531	01/25/2002	Jeffrey A. Lyon	003/241/SAP	2343

7590 08/04/2003

U. S. Army Medical Research and Materiel Command
ATTN: MCMR-JA (Ms. Elizabeth Arwine- Patent Atty)
504 Scott Street
Fort Detrick, MD 21702-5012

EXAMINER
BASKAR, PADMAVATHI

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 08/04/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/057,531	LYON ET AL.	
	Examiner	Art Unit	
	Padmavathi v Baskar	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 April 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-52* is/are pending in the application.

4a) Of the above claim(s) *1,2,15-47 and 49-52* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3-14 and 48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-52* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. The response filed 4/29/03 Paper # 10 has been entered into the record. New claims 48-52 have been added. Claims 1-52 are pending in the application.

Drawings

2. The drawings are objected for the reasons set forth on the enclosed PTO-948. A proposed drawing correction or corrected drawings are required in reply to this Office action to avoid abandonment of the application.

Information Disclosure Statement

3. The information disclosure statement has not been submitted in this application

Specification Informalities.

4. The disclosure is objected for lack of complete information in the specification. For example: on page 6, ATCC address and plasmid pETATpfMSP-1_{42} (3D7) accession number are missing.

Election/Restriction

5. Applicant's election with traverse of Group I in Paper # 10, 4/29/03 is acknowledged. Applicant elected Group I claims 3-14 drawn to DNA. New claim 48 has been added to the elected Group I invention along with the method claims. However, new claims 49-52 are drawn to non-elected invention, Group II (claims drawn to product by process and composition) invention. Therefore, only claims 3-14 and 48 are under examination.

6. Since no arguments put forth to support traversel, the requirement is still deemed proper and is therefore made FINAL. Claims 1-2, 15-47 and 49 -52 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected group.

Priority

7. This application claims domestic priority under 35, U.S.C. 119 (e) to provisional applications

60/264,535	1/29/01
60/347,564	10/26/01

The examiner has reviewed the applications and priority is accorded as of 1/29/01 to claims 3-14 and 48 since the provisional application 60/264,535 discloses a DNA sequence that encodes SEQ.ID.NO: 2 containing 431 amino acids.

Claim Rejections - 35 USC 112, first paragraph

8. The following is a quotation of the first paragraph of 35 U.S.C. 112

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 3-14 and 48 are rejected under 35 U.S.C. 112, first paragraph, as failing to provide an enabling disclosure without complete evidence that the claimed biological materials are known and readily available to the public or complete evidence of the deposit of biological materials.

The specification lacks complete deposit information for the deposit of the ATCC pETATpfMSP-1_{42} (3D7). It is not clear that pETATpfMSP-1_{42} (3D7) is known and publicly

available or can be reproducibly isolated from nature without undue experimentation. It is noted that this vector could be used in all methods even those claims which broadly recite a vector.

Because one skilled in the art could not be assured of the ability to practice the invention as claimed in the absence of the availability of the vector of the invention, a suitable deposit for patent purposes, evidence of public availability of the pETATpfMSP-1_{42} (3D7) of the invention or evidence of the reproducibility without undue experimentation of the pETATpfMSP-1_{42} (3D7) is required.

If the deposit has been made under the provisions of the Budapest Treaty, filing of an affidavit or declaration by applicant or assignees or a statement by an attorney of record who has authority and control over the conditions of deposit over his or her signature and registration number stating that the deposit has been accepted by an International Depository Authority under the provisions of the Budapest Treaty, that all restrictions upon public access to the deposit will be irrevocably removed upon the grant of a patent on this application and that the deposit will be replaced if viable samples cannot be dispensed by the depository is required. This requirement is necessary when deposits are made under the provisions of the Budapest Treaty as the Treaty leaves this specific matter to the discretion of each State. Amendment of the specification to recite the date of deposit and the complete name and full street address of the depository is required. As a possible means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit.

If the deposits have not been made under the provisions of the Budapest Treaty, then in order to certify that the deposits comply with the criteria set forth in 37 CFR 1.801-1.809, assurances regarding availability and permanency of deposits are required. Such assurance may be in the form of an affidavit or declaration by applicants or assignees or in the form of a

statement by an attorney of record who has the authority and control over the conditions of deposit over his or her signature and registration number averring:

(a) during the pendency of this application, access to the deposits will be afforded to the Commissioner upon request;

(b) all restrictions upon the availability to the public of the deposited biological material will be irrevocably removed upon the granting of a patent on this application;

(c) the deposits will be maintained in a public depository for a period of at least thirty years from the date of deposit or for the enforceable life of the patent of or for a period of five years after the date of the most recent request for the furnishing of a sample of the deposited biological material, whichever is longest; and

(d) the deposits will be replaced if they should become nonviable or non-replicable.

In addition, a deposit of biological material that is capable of self-replication either directly or indirectly must be viable at the time of deposit and during the term of deposit. Viability may be tested by the depository. The test must conclude only that the deposited material is capable of reproduction. A viability statement for each deposit of a biological material not made under the Budapest Treaty must be filed in the application and must contain:

1) The name and address of the depository;

2) The name and address of the depositor;

3) The date of deposit;

4) The identity of the deposit and the accession number given by the depository;

5) The date of the viability test;

6) The procedures used to obtain a sample if the test is not done by the depository; and

7) A statement that the deposit is capable of reproduction.

If the deposit was made after the effective filing date of the application for patent in the United States, a verified statement is required from a person in a position to corroborate that the pETATpfMSP-1_{42} ((3D7)) described in the specification as filed is the same as that deposited in the depository. Corroboration may take the form of a showing of a chain of custody from applicant to the depository coupled with corroboration that the deposit is identical to the biological material described in the specification and in the applicant's possession at the time the application was filed.

Applicant's attention is directed to In re Lundack, 773 F.2d. 1216, 227 USPQ 90 (CAFC 1985) and 37 CFR 1.801-1.809 for further information concerning deposit practice.

NOTE THE CURRENT ATCC DEPOSITORY ADDRESS

American Type Culture Collection, 10801 University Boulevard, Manassas, VA 20110-2209

Applicant is reminded to amend the specification accordingly.

Claim Rejections - 35 USC 112, second paragraph

14. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

15. Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is vague and indefinite in recitation of "a DNA sequence corresponds to SEQID.NO: 2" because SEQ.ID.NO: 2 is an amino acid sequence.

Objection

16. With regard to claim 3, the abbreviation "MSP -1_{42}" is used without definition upon its first appearance in the claims.

Claim Rejections - 35 USC 102

17. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

18. Claim 3 is rejected under 35 U.S.C. 102(b) as being anticipated by Kumar et al 1995, Molecular Medicine 1, 325-332.

The claim is directed to a recombinant vector comprising a DNA sequence encoding an MSP-1_{42}.

Kumar et al disclose a recombinant vector pGEX3 comprising a DNA sequence encoding MSP-1_{42} (see page 326, left column, third paragraph under Materials and Methods). Thus the prior art anticipates the claimed invention.

19. Claim 3 is rejected under 35 U.S.C. 102(b) as being anticipated by Chang et al 1996, Infection and Immunity 64: 253-261.

The claim is directed to a recombinant vector comprising a DNA sequence encoding an MSP-1_{42}.

Chang et al disclose a recombinant vector baculovirus comprising a DNA sequence (BV 42) encoding MSP-1_{42} (see page 254, left column, first paragraph under Materials and Methods) Thus, the prior art anticipates the claimed invention.

20. Claims 9-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Kumar et al 1995, Molecular Medicine 1, 325-332.

Claims are drawn to a method for producing and purifying recombinant P.falciparum MSP-1_{42} protein comprising growing a host cell containing vector expressing said protein, lysing said host cells to recover said recombinant protein.

Kumar et al disclose a method of producing and purifying recombinant MSP-1_{42} (see page 326, left column, third paragraph through right column under Materials and Methods) from P.falciparum. The recombinant plasmid pGEX3 was electroporated in to E.coli. Bacterial cells were grown in the presence of IPTG to induce the high expression of recombinant protein, said cells were lysed by sonication. Recombinant protein bound to a reduced glutathione –agarose column and eluted with 10mM reduced glutathione (see page 326left column through right column under protein purification of rGST-MSP1-$_{42}$. The recombinant MSP-1_{42} that recovered was used as a vaccine in Aotus Monkeys (see page 327, right column last paragraph). Thus the prior art anticipated the claimed invention.

Claim Rejections - 35 USC § 103

21. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

22. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

23. Claims 9-14 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kumar et al 1995, Molecular Medicine 1, 325-332 in view of Short Protocols in Molecular Biology Ed: Ausubel Publisher: John Wiley, especially see pages 10-59, 16-31, 16-32, 16-33 and16-34.

Claims are drawn to a method for producing and purifying recombinant P.falciparum MSP-1_{42} protein comprising growing a host cell containing vector expressing said protein, said expression of said vector is induced by IPTG at 24-27^{0}C, said host cells were lysed in the presence of imidazole and E.coli endotoxin was removed by application to a Ni-NTA column.

Kumar et al teaches a method of producing and purifying recombinant P.falciparum MSP-1_{42} (see page 326, left column, third paragraph through right column under Materials and Methods) from vector pGEX3. The recombinant plasmid was electroporated into E.coli. Bacterial cells were grown in the presence of IPTG to induce to produce recombinant protein, said cells were lysed (sonication) and recombinant protein was recovered. However, the prior art does not teach said using vector pETATpf MSP1-$_{42,}$ induction at 24-27^{0}C, host cells lysed in the presence of imidazole and E.coli endotoxin removed by application to a Ni-NTA column in said method. However, Ausubel teaches protein expression in various vectors including thioredoxin fusion proteins, growing the expression vectors containing DNA encoding proteins

that are induced by IPTG at various temperatures in the presence of fungicides, antibiotics and purifying proteins from E.coli containing pET vectors using Ni- NTA column (especially see pages 10-59, 16-31, 16-32, 16-33 and16-34) to remove endotoxin etc as it is routine in the art. Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to use a method for producing recombinant *plasmodium falciparum* protein as taught by Kumar and use the routine technology in the art including various temperatures to induce high yield of recombinant product, growing cells in large amounts in the presence of fungicides such as imidazole or other antibiotics, lysing cells and purifying the protein using NTA column as taught by Ausubel (see page 10-59) with a reasonable expectation of success because it would help in preparing pure recombinant MSP1-$_{42}$protein from any vector including pETATpf MSP1-$_{42}$. An artisan of ordinary skills would have been motivated in applying the methods of Kumar et al to the Ausuble methods to purify and obtain large quantities of soluble protein because the prior art suggests that protein could be used in a vaccine preparation (see Kumar's abstract) or in diagnostic assays. The claimed invention is prima facie obvious over Kumar et al in view of Ausuble absent any convincing evidence to the contrary.

24. Claims 4-8 appear to be free of prior art.

Status of Claims

25. No claims are allowed.

26. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padma Baskar whose telephone number is (703) 308-8886. The examiner can normally be reached on Monday through Friday from 6:30 AM to 4 PM EST

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Padma Baskar Ph.D.

7/30/03

NITA MINNIFIELD
PRIMARY EXAMINER
7/31/03